

Number/Name: P-18-0078 / [REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

Updated 8/22/2018 with POD for [REDACTED] (LOAEL of 100 mg/kg-day) and MOE calculations. See calculations below and updated conclusions in red. See Post-Focus memo for rationale of POD selection.

## SUMMARY INFORMATION

EPA estimated the human health hazard of this chemical substance based on its estimated physical/chemical properties and other structural information. EPA concludes there is low-to-moderate concern for human health hazard for the chemical substance.

Based on the hazard determination and available qualitative risk information, EPA concludes that there is risk for the PMN substance. The risk estimates for this PMN are for the intended conditions of use. Other conditions of use and their risks were not evaluated.

### Human Health Hazard:

- Absorption of the low MW fraction [REDACTED] is poor all routes (pchem).
- Concern for developmental toxicity, based on the presence of [REDACTED] of the PMN based on the average MW) in the chemical structure.
- Potential epoxide concerns are low, as [REDACTED] is expected to be present on each polymer; however, if made differently, there may be a higher percentage of [REDACTED] acids or epoxides that could change the hazard call.

### Human Health Risk:

- Risks were not identified for workers for developmental toxicity via dermal contact based on analogue data (MOE=1481, Benchmark MOE=1000)
- Risks were not identified for workers for developmental toxicity via inhalation based on analogue data (MOE=2128, Benchmark MOE=1000).
- Risks were not identified for general population for developmental toxicity based on analogue data (All MOEs>10,000, Benchmark MOE=1000).

### Testing Recommendations:

- OECD Testing Guideline 422, Combined Repeated Dose Toxicity Study with the Reproduction/Developmental Toxicity Screening Test, to clarify the concern for developmental toxicity to workers via inhalation and dermal exposure, and to the general population via drinking water ingestion and fugitive air inhalation.

**PART A**

SAT Date: 05 January 2018

SAT Chair: Tracy Behrsing

Health Assessor: Amy Babcock

QC Reviewer: Susan Laessig, 1/10/18

**Structure:**

PMN: P-18-0078		Submitter: [REDACTED]		Manu.	Import
Max. PV (KG): [REDACTED]		Binding Option Marked:		X	
MW: [REDACTED]	[REDACTED]	% < 500	[REDACTED]	% < 1000	CASNo [REDACTED]
PMN Structure			Prop.	Meas.	Est.
[REDACTED]			MP		
			BP		>500
			Pres.		at 760 mm Hg
			VP		<0.000001
			S-H2O		<0.000001
			log P		
[REDACTED]			Analogs: [REDACTED]		
USE: [REDACTED] Synthetic scheme: [REDACTED] Polymer Exemption case (E1) [REDACTED] All analogs are [REDACTED]			<input checked="" type="checkbox"/> other_uses  No other uses found.		

- CASRN: [REDACTED]
- Chemical Category:
  - Epoxides
- Chemical Category Health Concerns:
  - Cancer and reproductive effects based on data for several analogous chemicals. There is greater concern for primary epoxides, than for epoxides with substitutions on both of the epoxy carbons.

- **Category Testing Strategy:**
  - Lifetime cancer bioassay by the expected route of exposure.
  - 90-day subchronic with attention to pathology of the reproductive organs.
- **PMN Health Rating:**
  - 1-2
  - P3 B1 T2
- **SAT Key Words:**
  - UNCERT DEVEL
- **Absorption:**
  - Absorption of the low molecular weight fraction ( ) is poor all routes, based on physical/chemical properties.
- **SAT Health Summary:**

Based the presence of acids on the polymer there is an uncertain potential for developmental concerns. For the , this acid group would make up of the PMN based on the average MW. Based on the and average PMN molecular weight of , epoxide is expected to be present on each polymer and thus potential epoxide concerns are low. If made differently. there may be a higher percentage of acids or epoxides that could change the hazard call.
- **PMN Data: (study summary, POD)**
  - None submitted
- **Analog Data: (analog, structure, study summary, POD)**
  - None available

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(38) ANALOGS:			
PMN or CAS No.	Chem. Name	Structure	TSCA Y/N

- **Other Information:** (structural alert or component of interest, basis, etc.)
  - SDS
    - Not submitted
- **Point of Departure Selected and Basis:**
  - No POD available.

**Exposure Routes of Interest:**

- ☒ Inhalation
- ☒ Dermal
- ☒ Ingestion

## PART B

Focus Date: 22 January 2018

Focus Assessor: Amy Babcock

QC: Sailesh Surapureddi

### USES and EXPOSURES:

- **Uses:** [REDACTED] [REDACTED]  
[REDACTED]. Synthetic scheme: [REDACTED]
- **Worker Exposure:**
  - **Inhalation:** [REDACTED] mg/d (non-volatile)
  - **Dermal:** [REDACTED] mg/d
- **General Population Exposure:**
  - **Drinking Water:** [REDACTED] mg/kg/d
  - **Fish:** Below modeling thresholds
  - **Air/Inhalation:** [REDACTED] mg/kg/d = [REDACTED] ug/m3 (fugitive air)

Exposure Scenario <sup>1</sup>	Water						Landfill	Stack Air		Fugitive Air	
Release activity(ies) <sup>2</sup> ; exposure calculation(s) <sup>3</sup>	Drinking Water		Fish Ingestion		7Q10 <sup>4</sup>	PDM Days Exceeded	LADD	ADR	LADD	ADR	LADD
	ADR	LADD	ADR	LADD	CC = N/A			(24-hr conc.)	(Annual conc.)	(24-hr conc.)	(Annual conc.)
	mg/kg/day	mg/kg/day	mg/kg/day	mg/kg/day	µg/l	# Days		mg/kg/day (µg/m <sup>3</sup> )	mg/kg/day (µg/m <sup>3</sup> )	mg/kg/day (µg/m <sup>3</sup> )	mg/kg/day (µg/m <sup>3</sup> )
MFG: Max ADR	1.41E-02	---	---	---	---	---	---	---	---	[REDACTED] [REDACTED]	---
MFG: Max LADD	---	4.17E-06	---	---	---	---	---	---	---	---	---

- **Consumer Exposure:** No identified consumer exposures

### RISK CALCULATIONS:

#### Worker Calculations:

- Risks were not identified for workers for developmental toxicity via dermal contact based on analogue data (MOE=1481, Benchmark MOE=1000)

- Risks were not identified for workers for developmental toxicity via inhalation based on analogue data (MOE=2128, Benchmark MOE=1000).

Focus Worker Calculations MOE = (POD x Abs Rate) / ((PDR x Abs Rate) / BW) Acceptable MOE ≥1000										
Exposure Scenarios and Values <sup>1</sup>	POD= N/LOAEL (mg/kg/day)	POD Route Absorp . Adj <sup>2</sup>		Potential Dose Rate (mg/day)	Exposure Route Absorp Adj <sup>2</sup>	Structural Alert/ Component as % of PMN	Avg BW <sup>3</sup> All Adults, 80 (kg)		Margin of Exposure <sup>4</sup> (POD/PMN Dose)	Inhalation Fold <sup>5</sup> Factor <sup>5</sup> (Benchmark/ MOE)
WORKER RISK										
Highest/Worst Case Doses from Engineering Report										(LOAEL=1000)
Inhalation	( 100	x 100%	) ÷ (		x 100%	x	80	) =	2128	N/A
Dermal	( 100	x 100%	) ÷ (		x 15%	x	80	) =	1481	N/A
<sup>1</sup> Inhalation doses in mg/day are from the Engineering Report generated using ChemSTEER. Unless otherwise stated, the assumption is an 8-hr day. The EPA/OPPT 2-Hands Dermal Contact with Liquids Model calculates worker dermal exposures to a liquid. Model assumptions are: (1) surface area of contact equals two hands (1,070 cm <sup>2</sup> ); (2) high-end default value of quantity remaining on skin = 2.1 mg/cm <sup>2</sup> (low-end default = 0.7 mg/cm <sup>2</sup> ); (3) weight fraction of chemical in liquid; (4) 1 contact/worker-day; (5) no use of controls or gloves to reduce exposure; (6) exposure duration = 1 to 4 hours based expectation that worker will, at a minimum, thoroughly wash hands at lunch or end of the day.										
<sup>2</sup> Absorption adjustments for Focus - Assume 100% for POD; For Exposure. If risks, consider adjustments for absorption, etc.										
<sup>3</sup> USEPA 2011. Exposure factors handbook, final report, EPA/600-R09/052F, 2011, Chapter 8 Body Weight Studies, Table 8-1, Recommended Values for Body Weight <a href="http://www.epa.gov/ncea/efh/pdfs/efh-chapter08.pdf">http://www.epa.gov/ncea/efh/pdfs/efh-chapter08.pdf</a>										
<sup>4</sup> Benchmark (Acceptable) MOEs are 100 for NOAEL-based assessment and 1000 for LOAEL-based assessment.										
<sup>5</sup> Fold factor = value to be applied to bring INHALATION MOE up to acceptable level, used by the CEB Industrial Hygienist to determine respirator recommendations. NOAEL-based fold factor = 100/MOE; LOAEL-based fold factor = 1000/MOE.										

#### General Population Calculations:

- Risks were not identified for general population for developmental toxicity based on analogue data (All MOEs>10,000, Benchmark MOE=1000).

Focus General Population MOE Calculations												
MOE = (POD x Abs Rate) / ((PDR x Abs Rate) / BW) Benchmark (acceptable) MOE ≥1000												
Exposure Scenarios and Values <sup>1</sup>	POD= LOAEL (mg/kg/day)	POD Route Absorp Adj <sup>2</sup>		Exposure Acute Dose Rate (mg/kg/day)	Exposure Route Absorp Adj <sup>2</sup>	Multiplier for Sensitive Sub-populations <sup>4</sup>	Structural Alert/ Component as % of PMN		Margin of Exposure (POD/PMN Dose)			
GENERAL POPULATION RISK												
Highest/Worst Case Doses from Exposure Report									(LOAEL=1000)			
Drinking Water	( 100	x 100%	) ÷ (		x 100%	x 1.00	x	) =	177305			
Drinking Water	( 100	x 100%	) ÷ (		x 100%	x 4.17	x	) =	42519			
Inhalation	( 100	x 100%	) ÷ (		x 100%	x 1.00	x	) =	10000			
<sup>1</sup> General Population and Consumer ingestion Acute Dose Rates are from the Exposure Report and are generated using E-FAST which assumes a 100% absorption rate, and uses an average adult body weight of 80 kg. Consumer ADRs are generated using the Consumer Exposure Module within the E-FAST CBI version called "NCEM2" model.												
<sup>2</sup> Absorption adjustments for Focus: Assume 100% POD; if risks, consider adjusting for absorption, etc.												
<sup>3</sup> Benchmark (Acceptable) MOEs are 100 for NOAEL-based assessment and 1000 for LOAEL-based assessment.												
<sup>4</sup> Multiplier based on increased drinking water consumption for infants. Multiplier would be less for older populations, so this value is worst-case.												

- **Consumer Calculations:** Risks were not assessed as consumer exposures are not expected.